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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,226

01/20/2004

Philip C. Gevas

1102865-0031 CON

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04/19/2006

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/762,226	Applicant(s) GEVAS ET AL.	
	Examiner Susan Ungar	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on February 5, 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. The Amendment filed February 5, 2006 in response to the Office Action of November 1, 2005 is acknowledged and has been entered. Previously pending claims 2-3 have been amended. Claims 1-5 are currently being examined.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, Figure 1 discloses sequences which are not identified by sequence identifiers, either in the Brief Description of the Figures or on the Figure itself. Examiner has made an effort to identify these informalities but applicant must carefully review the specification to identify and indicate where other sequences which are not identified by sequence identifiers may be found. Appropriate correction is required.

Applicant is given the period of reply to this communication within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are being maintained:

***Claim Rejections - 35 USC 112***

5. Claims 1-5 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed November 1, 2005, Section 6, pages 3-7.

Applicant argues that Examiner's argument that the specification does not disclose an example of G17Gly-dependent tumor is erroneous and argues that DHDK12 is a G17Gly-dependent tumor cell line. The argument has been considered but has not been found persuasive as nothing in the teachings of the art of record of the specification as originally filed discloses that DHDK12 is a G17Gly-dependent tumor cell line. In particular, the specification teaches at the paragraph bridging pages 20-21 that the "neutralization of serum-associated gastrin contributed to reduced tumor growth", clearly demonstrating that not only Gly17 in its amidated or glycine extended forms but also gastrin is effective at stimulating tumor growth. Thus, it is clear that although amidated Gly 17 and the glycine extended form of Gly17 stimulate the growth of the tumor, the tumor is not dependent upon any one of these moieties for its growth. Further, it is noted that, although not drawn to medical applications, the Cambridge Dictionaries Online at <http://dictionary.cambridge.org/define.asp?key=20825&dict=CALD> specifically teach that "dependent" is understood to mean "needing the support of something.... In order to continue existing or operating". Clearly, given that gastrin clearly stimulates the growth of the tumor, the tumor is not dependent upon either of Gly17 in its amidated or glycine extended forms. Thus, Applicant has not provided a single example of a Gly17Gly dependent tumor.

Applicant further argues that Seva et al, of record teaches the role of G17Gly in the stimulation of pancreatic tumor cell line ARA-2J which Applicant suggests is a Gly17Gly-dependent tumor as evidence that the existence of G17Gly-dependent tumors was recognized not only in the present specification but also in the art at the time the invention was filed. The evidence and argument has been considered but has not been found persuasive. Although a review of the Seva et al reference discloses that the cell line is stimulated by Gly17Gly, the review of the Seva et al reference does not reveal any suggestion or guidance that suggest that the cell line is Gly17Gly-dependent.

Applicant points to Koh et al (Cancer Research, 2004, 64:196-201) to provide evidence that the existence of G17Gly-dependent tumors was known in the art prior to the present invention. The argument has been considered but has not been found persuasive since Koh et al was published 8 years after the priority date of the instant application. Further, a review of the Koh reference clearly reveals that the tumors assayed were not G17Gly-dependent since on page 198, col 2 the authors specifically state that "In this study, we present evidence that the glycine-extended gastrin can contribute to the growth and progression of lung cancer."

Applicant argues that the specification teaches how to recognize a G17Gly-dependent tumor by assessing G17 and G17Gly levels. The argument has been considered but has not been found persuasive because it is not clear how assessing the levels of these peptides can demonstrate that tumor growth or progression are dependent upon those peptides.

Applicant further argues that successful cancer vaccines are known in the art and points to Berd et al. (Cancer Research, 1986, 46:2572-2577). The argument has been considered but has not been found persuasive because a review of the

Berd et al reference reveals that the reference is drawn to vaccination with autologous melanoma cells in combination with CY, wherein 2 of the 19 patients treated had a significant clinical response. The instantly claimed invention is drawn to vaccination, with a peptide, against gastrointestinal tumors while the Berd et al reference is drawn to vaccination with an autologous melanoma cell in combination with CY, thus, the Berd et al vaccine method is not commensurate in scope with the instantly claimed method and does not enable the claimed method.

Applicant argues that the predictability of the claimed method is based on additional cell line data published in the art. The argument has been considered but has not been found persuasive because the references do not teach that the cell lines used were G17Gly-dependent tumor cells and thus the prior art is not commensurate in scope with the claimed invention.

Applicant argues that the specification provides information on how to make and use the vaccine of the present invention and that US Patent No. 5,023,077 specifically teaches how to make and administer the anti-G-17 vaccine. The argument has been considered but has not been found persuasive because Applicant has not taught the critical G17Gly-dependent tumor required by the claims. The arguments have been considered but have not been found persuasive and the rejection is maintained. It is noted that the rejection may be obviated, for example, by amending claim 1 to recite "A method for the treatment of gastrointestinal tumors whose growth is stimulated by glycine-extended gastrin-17".

6. Claims 1-5 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed November 1, 2005, Section 7, pages 7-10.

Applicant argues that two actual examples of the species of the genus of G17Gly-dependent tumors are disclosed in the specification. Applicant further argues that the DHDK12 cell line has been accepted as a representative member of the genus of G17Gly-dependent tumors. The argument has been considered but has not been found persuasive for the reasons set forth previously and above. Further, neither the art of record nor the specification as originally filed disclose or demonstrate that the DHDK12 cell line has been accepted as a representative member of the genus of G17Gly-dependent tumors. The arguments have been considered but have not been found persuasive and the rejection is maintained. It is noted that the rejection may be obviated, for example, by amending claim 1 to recite "A method for the treatment of gastrointestinal tumors whose growth is stimulated by glycine-extended gastrin-17".

7. Claims 1-5 remain rejected under 35 USC 112, second paragraph for the reasons previously set forth in the paper mailed November 1, 2005, Section 8, page 11.

Applicant argues that one of ordinary skill in the art, after reading the specification, would readily understand that the term "glycine-extended gastrin-17-dependent gastrointestinal tumors" relate to tumors stimulated by G17Gly. Therefore, Applicants maintain that the term "-dependent" is clear and definite. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted. Further, as set forth above, the general population, and certainly those of ordinary skill in the art understand the term "dependent" to mean "needing the support of something.... in order to continue existing or operating. Given the lack of definition in the specification, given the teachings of the specification, the metes

and bounds of the term are unclear. Applicant's arguments have not been found persuasive and the rejection is maintained. It is noted that the rejection may be obviated, for example, by amending claim 1 to recite "A method for the treatment of gastrointestinal tumors whose growth is stimulated by glycine-extended gastrin-17".

***New Grounds of Rejection***

***Claim Rejections - 35 USC 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-5 are rejected under 35 USC 102(e) as being anticipated by US Patent No. 5,785,970 as evidenced by Blackmore et al, (Int. J. Cancer, 1994,57:385-391).

The claims are drawn to a method for treatment of glycine-extended gastrin-17-dependent gastrointestinal tumors, comprising administering to a mammal a therapeutically effective amount of an anti-G17 immunogenic composition (claim 1 which induces antibodies that bind and neutralize amidated and glycine-extended gastrin-17 (claim 2), wherein the gastrointestinal tumors contain CCK-B receptors (claim 3), wherein the gastrointestinal tumors are colorectal adenocarcinomas (claim 4), wherein the mammal is a human (claim 5)



Blackmore et al teach that cell line HCT-116 is a colon adenocarcinoma cell line (see abstract) and that antagonists to gastrin/CCK receptor, also known as CCK-B receptor, inhibit gastrin dependent growth of the cells. Clearly demonstrating that the cell line comprises CCK-B receptors.

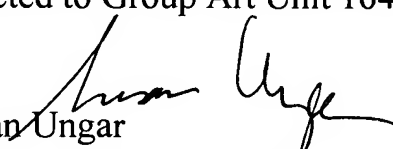
US Patent No. 5,785,970 claims a method of treating of a gastro-intestinal disorder, comprising administering to a mammal a therapeutically effective amount of an anti-G17 immunogen comprising a fragment of the N-terminal amino acid sequence of heptadecagastrin (claim 1), wherein the mammal is a human (para 4 of the Description of the invention), wherein said immunogen is capable of eliciting a sufficient titer of antibodies in the patient which selectively bind and neutralize the patients own G17 (claim 4) wherein the disease is a gastrin-induced tumor (claim 5) wherein the peptide consists essentially of pGlu-Gly-Pro-Trp-Leu-Glu-Glu-Glu-Glu (claim 11). It is noted that inherent in the administration of an immunogen is a composition comprising said immunogen. Further, the reference exemplifies the treatment of mammals comprising HCT-116 colon adenocarcinoma xenograft tumors which are treated by administering said immunogen (see Example 6).

Although the reference does not teach that the method is drawn to the treatment of glycine-extended gastrin-17-dependent gastrointestinal tumors, the method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering to a mammal a therapeutically effective amount of an anti-G17 immunogen/immunogenic composition comprising an immunogen that is identical to the one exemplified in the instant specification (see Figure 1) to the same population thus the claimed method is anticipated because the method will inherently lead to treatment of glycine-extended gastrin-17-dependent gastrointestinal tumors. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

10. No claims allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

  
Susan Ungar  
Primary Patent Examiner  
April 7, 2006